Special 510(k) Summary
OASYS® System – Transition Rod LE

Proprietary Name:	Stryker Spine OASYS™ System
Common Name:	Spinal Fixation Appliances
Proposed Regulatory Class:	Class II 21 CFR 888.3050: Spinal Interlaminal Fixation Orthosis
Device Product Code:	87 KWP: Appliance, Fixation, Spinal Interlaminal
Official Contact :	Tiffani D. Rogers Regulatory Affairs Manager Stryker Spine t: 201-760-8206 f: 201-760-8406 email: tiffani.rogers@stryker.com
For Information Contact:	Susan Frank, Esq. Regulatory Consultant 2 Pearl Court Allendale, NJ 07401 Telephone: (201) 760-8100 Fax: (201) 760-8464 Email: Susan.Frank@Styker.com
Date Summary Prepared:	June 15, 2011
Predicate Device Identification	Stryker Spine OASYS® System: K032394, K052317, K062853, K072568. K080143, K093670, K101183

Predicate Device Description

The Stryker Spine OASYS® System is comprised of rods, polyaxial screws, bone screws, hooks,

connectors, and occiput plates. The components are available in a variety of lengths in order to accommodate patient anatomy. The components are fabricated from Titanium alloy and CP Titanium and are provided non-sterile. The subject system also offers Vitallium® rods. The Stryker Spine OASYS® System can be linked to the Stryker Spine Xia® family and Xia 4.5 Systems and SR90D System.

Description of Device Modification
This Special 510(k) submission is intended to introduce a line extension to the predicate OASYS™ System. The proposed line extension consists of the transition rod.

Intended Use:
When intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (Occiput-T3), the STRYKER Spine Oasys System is intended for:

- Degenerative Disc Disease (as defined by neck and back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Spondylolisthesis
- Spinal Stenosis
- Fracture/Dislocation
- Atlanto/axial fracture with instability
- Occipitocervical dislocation
- Revision of previous cervical spine surgery
- Tumors

When used with the occipital plate, the bone screws are limited to occipital fixation only. The bone screws are not intended to be used in the cervical spine.

The use of the polyaxial screws is limited to placement in the upper thoracic spine (Tl -T3). They are not intended to be placed in the cervical spine.

The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C I-T3) spine.

The Stryker Spine OASYS® System can be linked to the Xia® System, SR90D System and Xia® 4.5 Spinal System via the rod-to-rod connectors and transition rods.

The Stryker Spine OASYS® System can also be linked to the polyaxial screws of Xia® II and Xia® 3 System via the saddle connector.

Statement of Technological Comparison:

Documentation is provided which demonstrates that the new component of the Stryker Spine Oasys System to be substantially equivalent to the predicate devices in terms of material, design, mechanical performance and indications for use. Static and Fatigue Compression Bending, and Static and Fatigue Torsion Bending, testing, per ASTM F1717 were conducted on the Oasys System components. The results obtained from these tests were compared to those of a predicate system to demonstrate substantial equivalence, as recommended by the "Guidance for Industry & FDA Staff Spinal System 510(k)s, May 3, 2004."

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN 19 2012

Stryker Spine
% Ms. Soraya King
Regulatory Affairs Specialist
2 Pearl Court
Allendale, New Jersey 07401

Re: K111719
Trade/Device Name: Stryker Spine OASYS® System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: KWP
Dated: December 23, 2011
Received: December 27, 2011

Dear Ms. King:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111719

Device Name: Line Extension to the Stryker Spine OASYS® System

Indications for Use:

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When used with the occipital plate, the bone screws are limited to occipital fixation only. The bone screws are not intended to be used in the cervical spine.

The use of the polyaxial screws is limited to placement in the upper thoracic spine (T1 -T3). They are not intended to be placed in the cervical spine.

The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C I-T3) spine.

The Stryker Spine OASYS® System can be linked to the Xia® System, SR90D System and Xia® 4.5 Spinal System via the rod-to-rod connectors and transition rods.

The Stryker Spine OASYS® System can also be linked to the polyaxial screws of Xia® II and Xia® 3 System via the saddle connector.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K111719